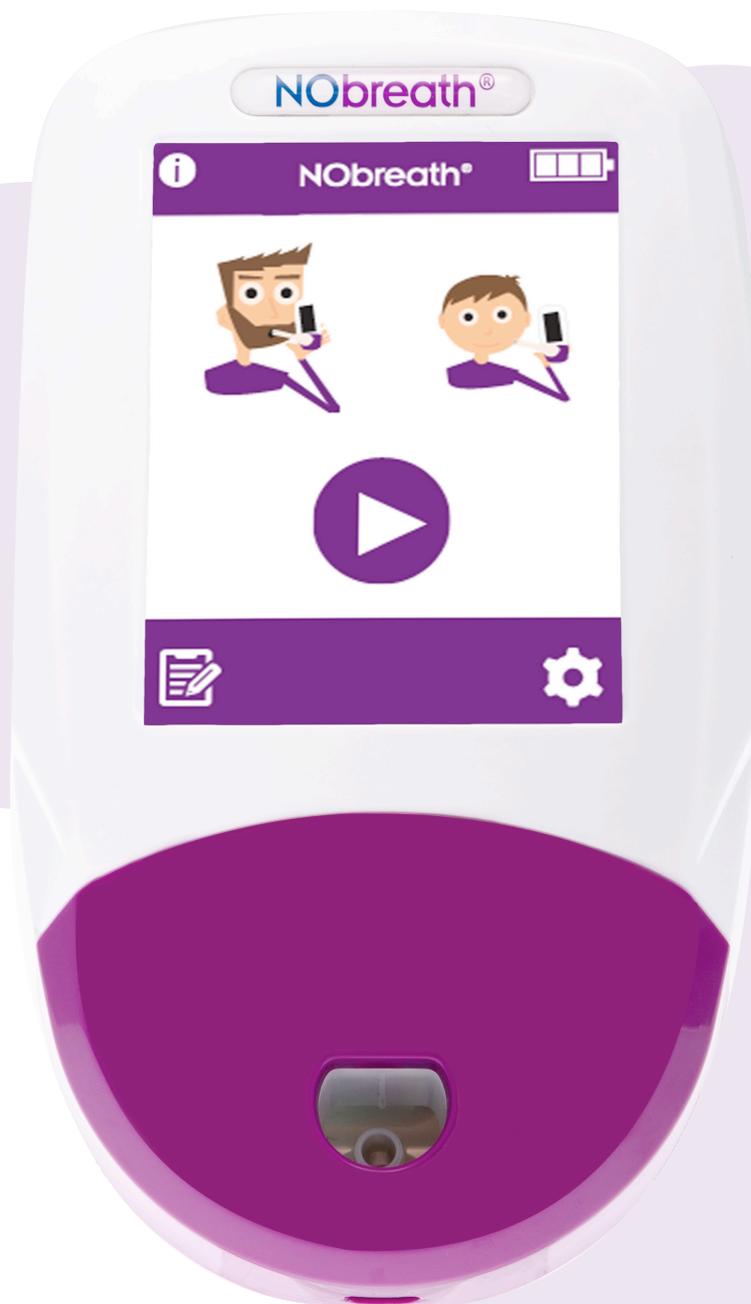


NObreath[®]

Fractional Exhaled Nitric Oxide (FeNO) Monitor

User Manual



*Aids in the diagnosis & management of asthma,
one breath at a time.*

Important Information/Reminders

NOTE: Only technical data and no patient data is collected by Bedfont®

NOTE: The NObreath® should be charged for a minimum of 4 hours before first use.

NOTE: The default PIN for the NObreath® is 0000. Bedfont strongly advises that this PIN is changed upon installation and set-up of the device.

WARNING: Please read the manual before use.

WARNING: Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the electrochemical sensor inside.

WARNING: Under no circumstances should the instrument be immersed or splashed with liquid.

WARNING: Breath tests must only be carried out with Bedfont accessories. Failure to do so may cause incorrect readings.

WARNING: The mouthpieces are single patient use only and can be used for a maximum of 3 tests. Further re-use could cause incorrect readings and could increase the risk of cross infection. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.

WARNING: Please be advised that the NObreath® Mouthpiece is single-patient-use only. Re-use of this mouthpiece can increase the risk of cross-infection and may result in decreased accuracy of results.

WARNING: Patients should exhale for the duration of time indicated by the monitor during a breath test. Failure to do so may cause incorrect readings.

WARNING: To ensure a breath sample is taken at the correct flow rate, the monitor must be held upright at all times during a breath test.

WARNING: Do not block the exhaust ports on the device at any time. Blocking the exhaust ports may cause erroneous readings.

CAUTION: Ensure the monitor is used within the stated operating temperature and humidity ranges. Operating temperature is 15-30°C. Operating humidity is 20-80% RH (non-condensing).

CAUTION: Portable and mobile RF communications equipment can affect the NObreath®.

CAUTION: A great way to keep the NObreath® charged when not in use is to use the docking station included. This can be connected via the mains adapter supplied, or plugged into a working USB port, to ensure the NObreath® has charge for when it's needed.

NOTE: When selecting an accessory for the NObreath® monitor, please be advised that an accessory not recommended by Bedfont® may result in loss of performance and damage to your NObreath® device. The product warranty does not cover product failure or damage resulting from use with non-approved accessories.

NOTE: See Bedfont’s infection control and maintenance guidelines for further information on infection control.

NOTE: Please do not attempt to modify the equipment in any way or use accessories not specified by the manufacturer. Any attempt to do so, will invalidate the warranty and may compromise the safety of the device.

NOTE: Bedfont® will make available on request service training to appropriately qualified personnel.

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Introduction

The User Manual provides instructions on how to operate NObreath® FeNO monitor and its accessories. It contains relevant information about the monitor, its uses and its care, including step-by-step instructions with screens and illustrations.

Definitions

WARNING: indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury.

CAUTION: indicates a potentially hazardous situation, which, if not avoided, may result in damage to the device.

NOTE: used to call attention to notable information that should be followed during use.

Compliance

NObreath® is CE marked according to the Medical Device Directive 93/42/EEC.

Please refer to the 'Safety Information' section of this manual for more information on the compliance of the NObreath®.

Intended Use

The NObreath® is a breath nitric oxide (NO) test system intended to measure fractional exhaled nitric oxide (FeNO) in parts per billion (ppb) in exhaled breath.

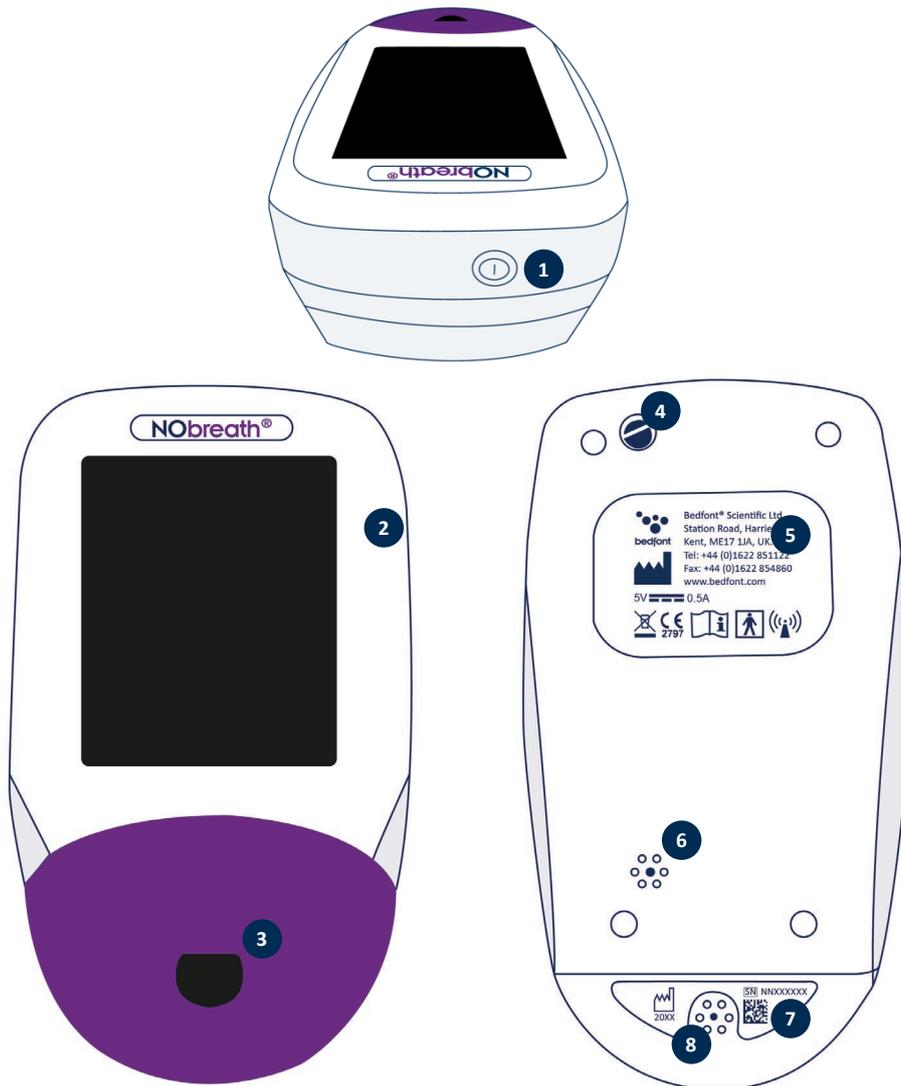
The measurement is taken to evaluate airway inflammation and should be used in conjunction with other clinical and laboratory evaluations where appropriate when making a diagnosis or treatment plan.

The measurements are intended for interpretation by healthcare professionals and for use in a healthcare environment, where patients will complete measurements under supervision.

Contraindications

There are no known contraindications.

Instrument Layout



1. ON/OFF switch
2. Touchscreen
3. Mouthpiece aperture
4. ¼ turn lock

5. Manufacturer label
6. Exhaust port
7. Serial label
8. Exhaust port

Installation and Set-up

NOTE: The NObreath® should not be operated in an environment outside of the temperature or humidity ranges stated in the technical specification.

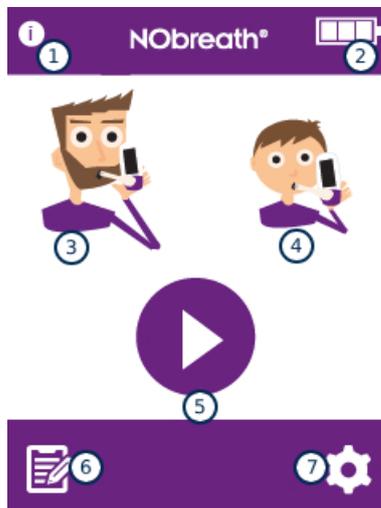
The NObreath® should be charged for 4 hours prior to first use.

The default PIN is 0000. It is strongly recommended to change this prior to first use – please refer to the ‘Change PIN’ section of this manual for instructions.

When selecting an accessory for the NObreath® monitor, please be advised that an accessory not recommended by Bedfont® may result in loss of performance and damage to your NObreath® device. The product warranty does not cover product failure or damage resulting from use with non-approved accessories.

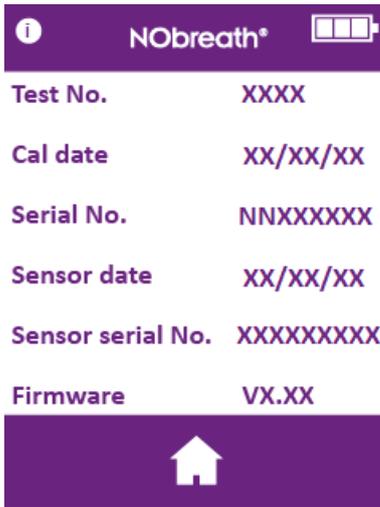
WARNING: Please be advised that the NObreath® Mouthpiece is single-patient-use only. Re-use of this mouthpiece can increase the risk of cross-infection and may result in decreased accuracy of results

User Interface



Home Screen

1. Information button
2. Battery status
3. Adult breath test
4. Child breath test
5. Demo mode
6. Patient profiles
7. Settings



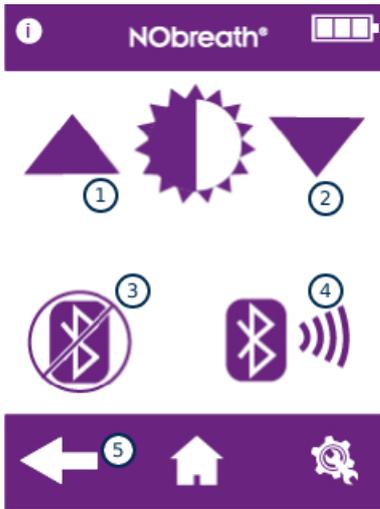
The information screen displays information about the monitor and sensor.



Settings Menu Page 1

1. Date and time options
2. Test log
3. Change PIN number
4. Enable/disable PIN use
5. Change flow-meter style
6. Start ambient air test
7. Service Area
8. Home button
9. Go to Settings Menu Page 2

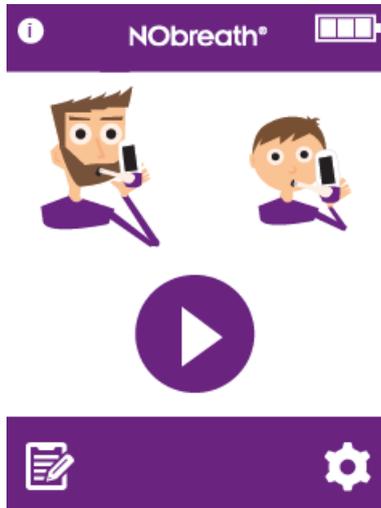
NOTE: *The Service Area must only be accessed by trained personnel.*



Settings Menu Page 2

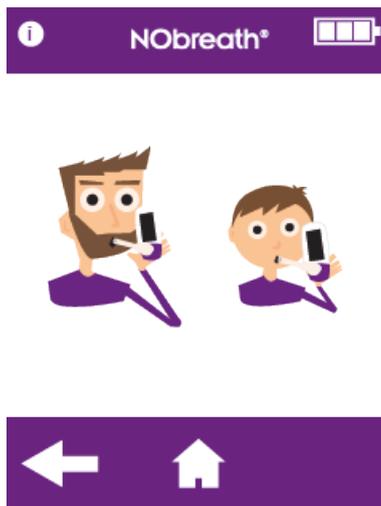
1. Increase screen brightness
2. Decrease screen brightness
3. Enable/disable Bluetooth
4. Bluetooth pairing PIN
5. Go to Settings Menu Page 1

Demo mode

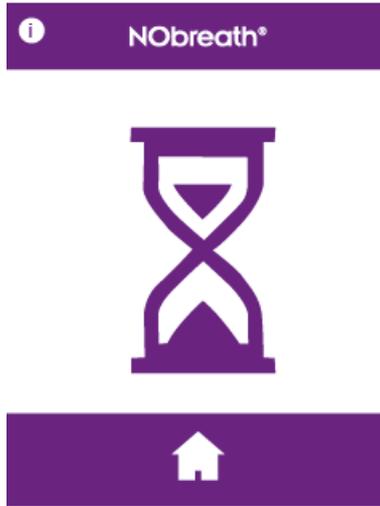


The NObreath® has an in-built demonstration video of the breath test process. It is recommended to watch this video prior to using the device for the first time. This demo can also be used to explain to patients how the test will run, prior to performing one.

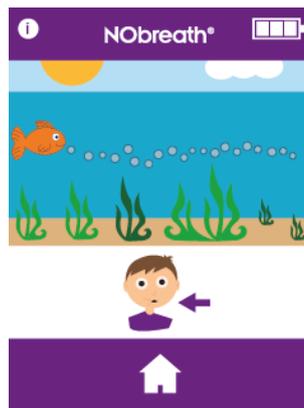
Press the demo icon to begin.



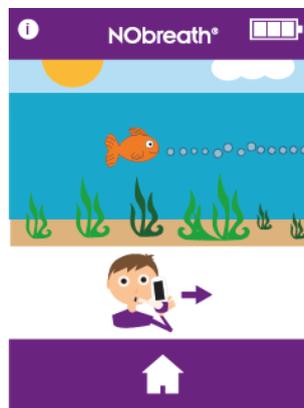
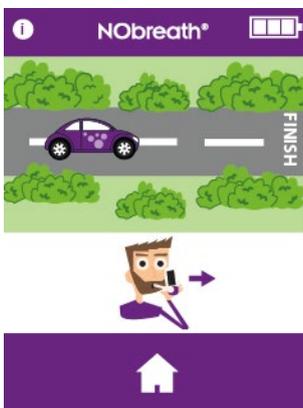
Select either the adult or child patient.



The zero screen will briefly display as in a real test.



A demonstration will run through the breath test process.



The whole test will be shown, but at an accelerated speed.



Only a successful test will be demonstrated.



10
ppb NO



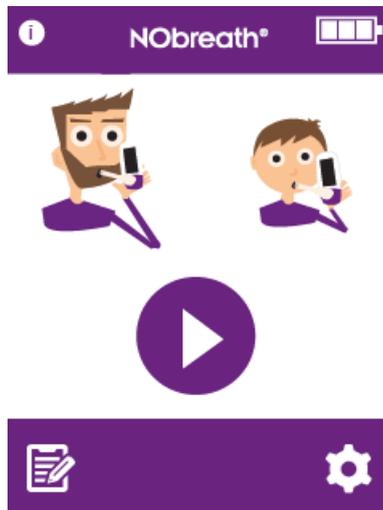
10
ppb NO



Once the result is displayed, the demo is complete.

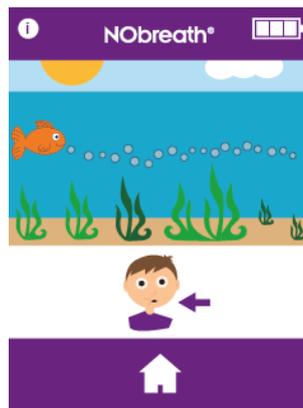
Press the home icon to return to the home screen.

Performing a Breath Test



Open and insert a new mouthpiece into the NObreath® monitor.

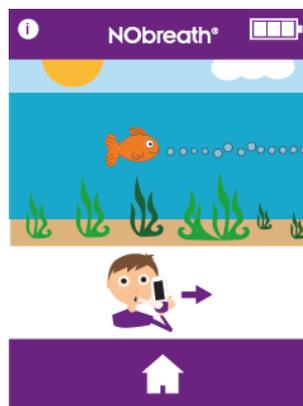
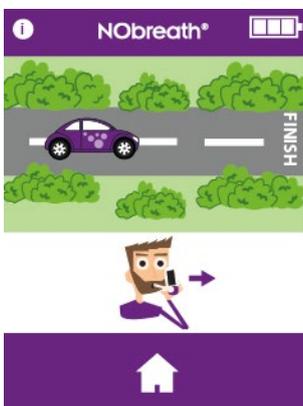
To start a breath test, select either the adult or child patient.



As prompted onscreen, take a deep breath.

NOTE: Do not inhale through the mouthpiece.

Press the home button at any time to cancel the breath test.

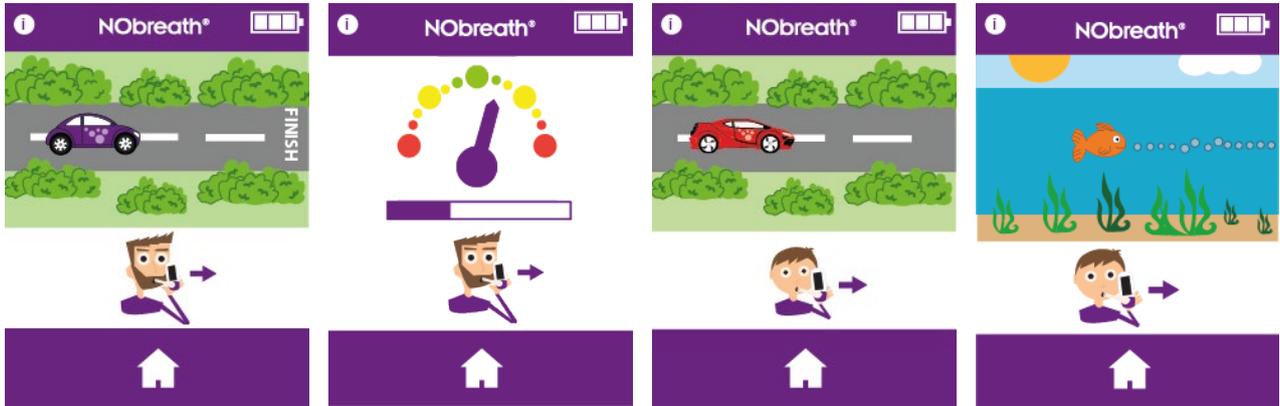


When the exhale icon displays, keep the monitor upright and blow gently into the mouthpiece.

NOTE: Make sure the vent holes are not covered.

The exhalation time is approximately 12 seconds for an adult and 10 for a child.

The onscreen flow meter will guide the patient on the exhalation rate:



Keep the car in the middle of the road.

Keep the dial in the green area.

Keep the car in the middle of the road.

Follow the bubbles.

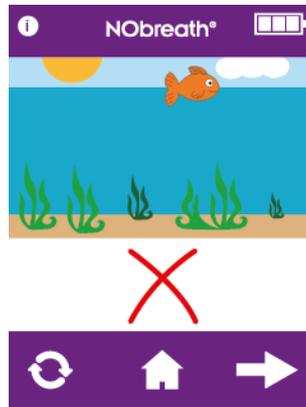
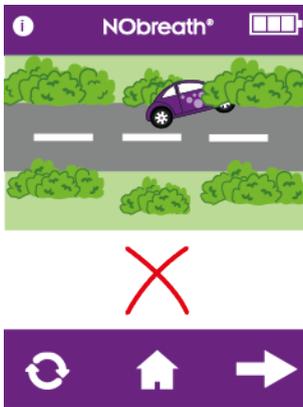


A green tick onscreen indicates a successful test.



The results will then be shown onscreen in ppb.

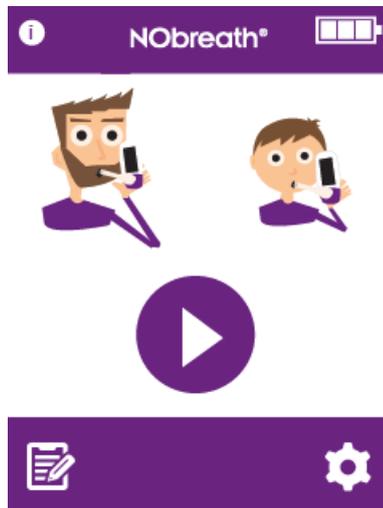
Return to the home screen by pressing the home button or save the result to a patient profile.



If the patient exhales outside of the exhalation guidelines, the test will beep before indicating a fail and a red cross will appear.

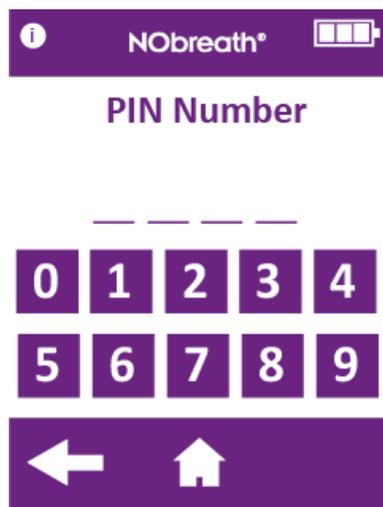
Press the retry icon to retake the test or the next arrow to view the result.

Patient profiles



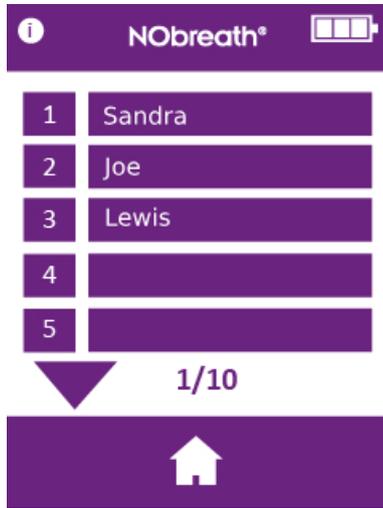
The NObreath® is designed to be capable of storing up to 25 results in up to 50 patient profiles.

Press the profiles icon to access patient profiles.

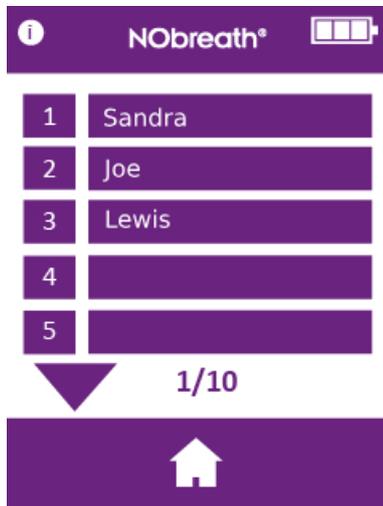


If the PIN has not been entered in the last 30 minutes, the 4-digit code will be required before the patient profiles can be accessed.

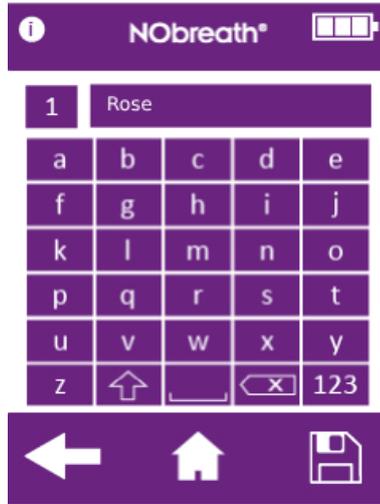
NOTE: *If the PIN has been forgotten, please contact Bedfont® or its local distributor to reset it.*



A list of patient profiles will show onscreen.



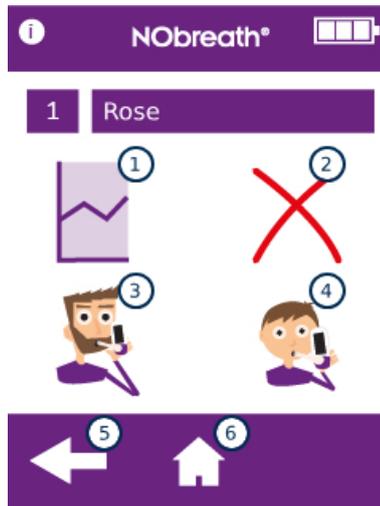
Create a new patient profile
To create a new profile, choose an empty name slot.



Use the keypad to enter a name or reference.

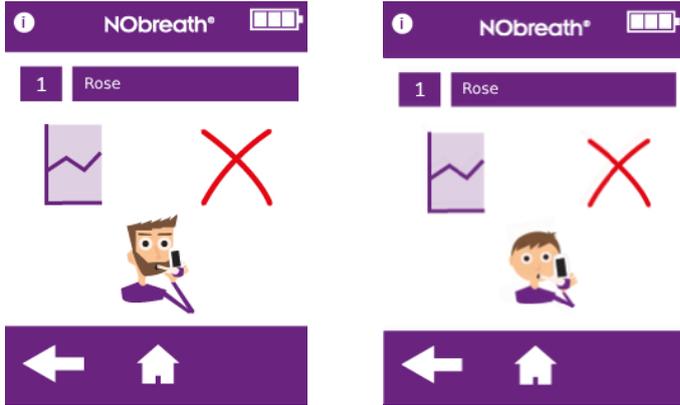
Click the save icon to create the profile.

To cancel, press the back arrow to return to the list of profiles or the home icon to return to the main screen.

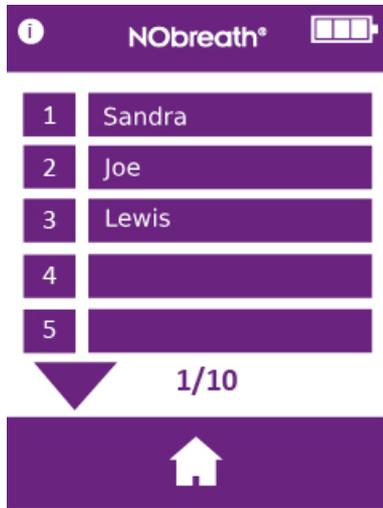


Once the profile has been created the following options will become available:

1. See a graph of results
2. Delete the patient profile
3. Take an adult breath test
4. Take a child breath test
5. Return to the profile list
6. Return to the main screen

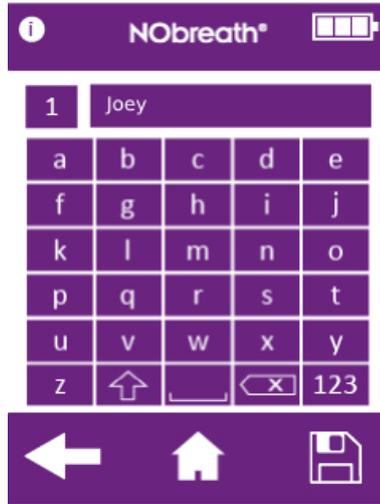


Once an adult or child breath test has been selected, the profile will only offer that breath test mode in future.



Edit a patient profile

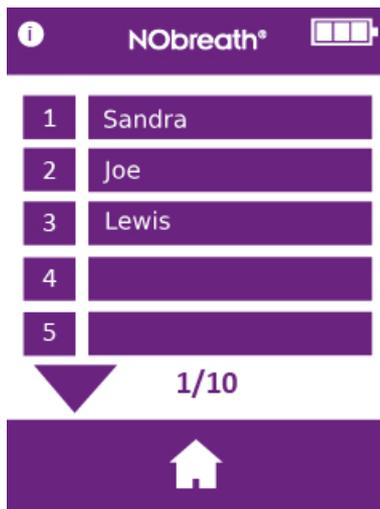
To edit a patient's profile, select their name/ID from the list.



Use the keypad to edit the profile.

Click the save icon to save the changes.

To cancel, press the back arrow to return to the list of profiles or the home icon to return to the main screen.



Delete a patient profile

Select the patient that will be deleted to load their profile.



Press the red 'x' to delete the patient profile.



Press the tick to confirm.

The profile will be deleted the profile screen will be displayed.

Maintenance

Lifetime of a NObreath®

The NObreath has unlimited uses. Subject to correct use, maintenance and service. Tested up to 29,000 tests.

Routine maintenance

1. Mouthpieces are to be replaced after every patient.
2. Hands should be washed regularly in accordance with infection control practice.
CAUTION: Do not use sanitising products containing alcohol as this may damage the sensors.
3. Only use accessories approved by Bedfont®.
CAUTION: Use of accessories not approved by the manufacturer will invalidate the warranty and may compromise the safety of the device.
4. It is best practice to not let the battery run flat. If this occurs, the device may need calibration. Please contact Bedfont or its local distributor for advice.

Servicing

1. The NObreath® should be calibrated annually or the NO sensor should be replaced.
2. The NO scrubber should be replaced annually.
3. The NO sensor, breath drying cartridge and the pump should be replaced every 5 years

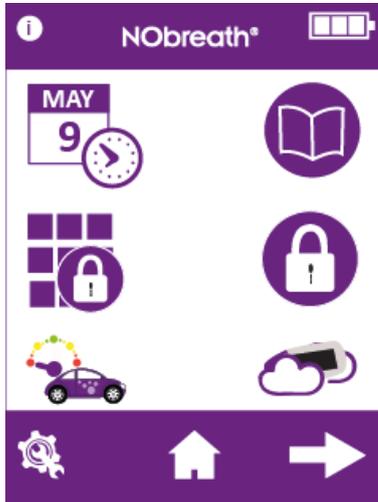
WARNING: Do not open the NObreath® device. This could result in bodily harm and a void in warranty. Servicing should only be carried out by a Bedfont® trained representative.

Cleaning

1. Bedfont® recommends wiping the instrument's external surfaces with a product specifically developed for this purpose. Bedfont® provides instrument cleaning wipes. The device or consumables cannot be sterilised. It is recommended that wipes are used once and for one surface only. The NObreath® device should be cleaned for initial use and after each patient use.
CAUTION: Do not use any substances containing alcohol on or near the NObreath®.

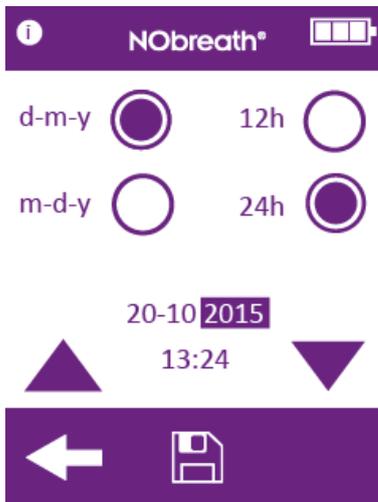
Under no circumstances should the instrument be immersed in liquid or splashed with liquid.

Settings



Change the date/time

To change the date or time, press the edit date/time icon on the 1st page of the settings menu.

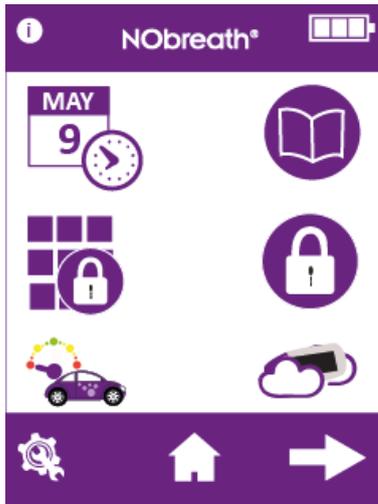


Select either **d-m-y** or **m-d-y** for the date format and **12h** or **24h** for the time format. The purple circle, , indicates the selected option.

To adjust the date/time, select the number and it will become highlighted. Use the arrows to change as desired.

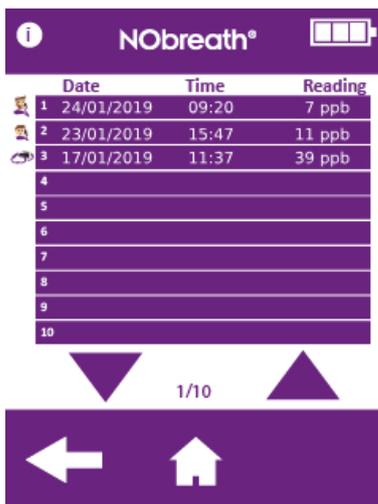
Press the save button to keep the changes.

To cancel, press the back arrow to return to the settings menu.



Test log

To access the test log, press the log icon on the 1st page of the settings menu.



The most recent test results are automatically saved in the log and the NObreath can store 250 at a time.

Use the arrows to scroll through the log.

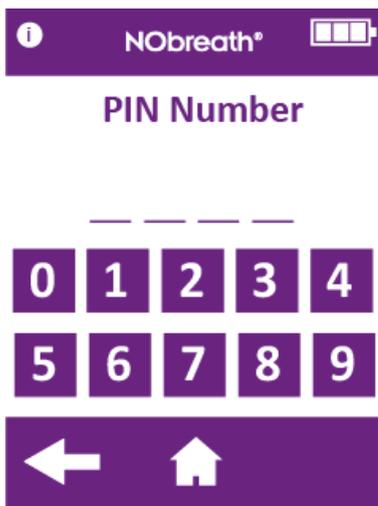
Press the back arrow to return to the settings menu or the home icon to return to the main screen.



Change PIN

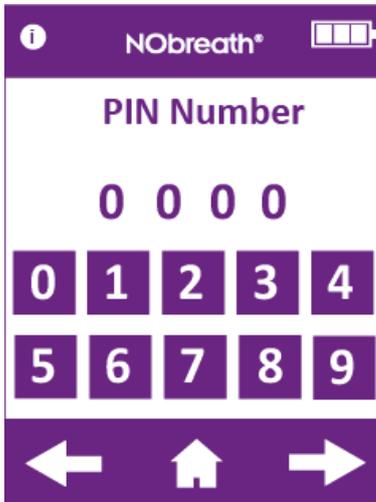
Each device is pre-set to the PIN code 0000. It is highly recommended that the PIN is changed to a memorable 4 digit number.

To change the PIN number, press the change PIN icon from the 1st page of the settings menu.

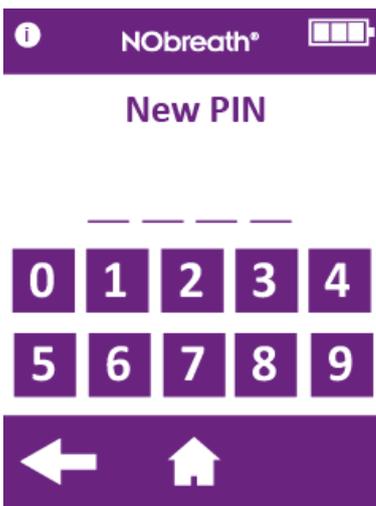


A prompt will ask for the current PIN to be entered.

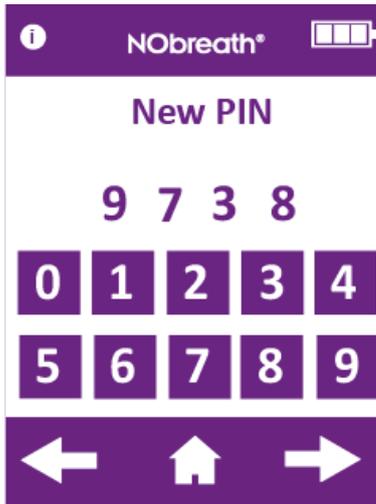
If the PIN has been forgotten, please contact Bedfont® or its local distributor to reset it.



Enter the current PIN and press the next arrow to proceed.



A prompt will then ask for a new PIN number to be entered.



Enter a new memorable 4 digit code and press the next arrow to continue



A prompt will ask for the new PIN number to be re-entered for confirmation.



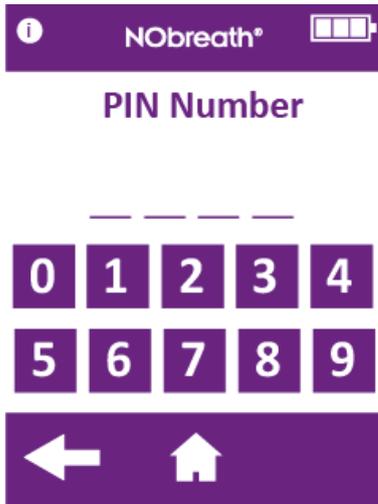
Re-enter the PIN to confirm the new 4 digit code and press the tick to register the change.

To cancel, press the back arrow to return to the settings menu or the home icon to return to the main screen.



Enable/disable PIN

To disable the PIN, press the enable/disable PIN icon on the 1st page of the settings menu.



A prompt will ask for the PIN number to be entered in order to disable the PIN function.



Once the PIN function is disabled, it will be crossed out in the settings menu.

To re-enable the PIN function, simply press the enable/disable button again and re-enter the PIN to confirm.

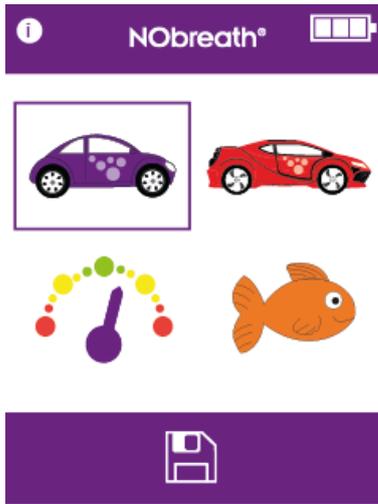


Change flow-meter style

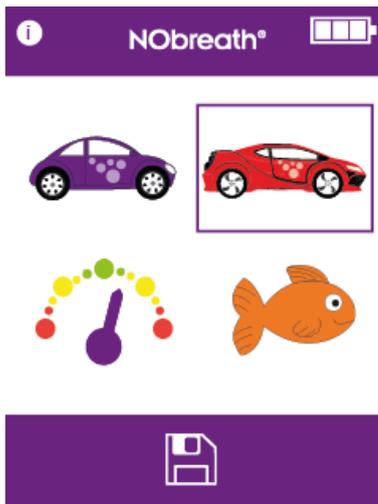
To change the flow-meter style, press the flow-meter button on the 1st page of the settings menu.



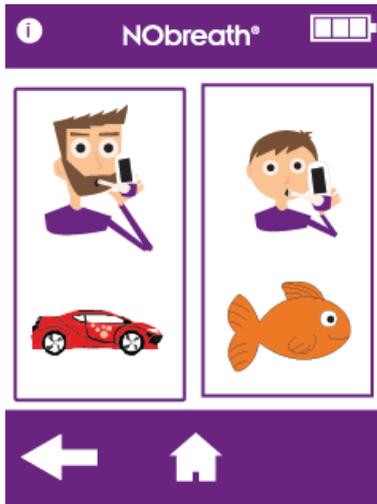
Select either the adult or child test mode to change the flow-meter style.



The current flow-meter style will be highlighted.



Select the new style and press the save icon to register.



The new flow-meter style will now be used for that breath test mode and the relevant demo mode.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.



Ambient air test

To perform an ambient air test, press the ambient test icon on the 1st page of the settings menu.

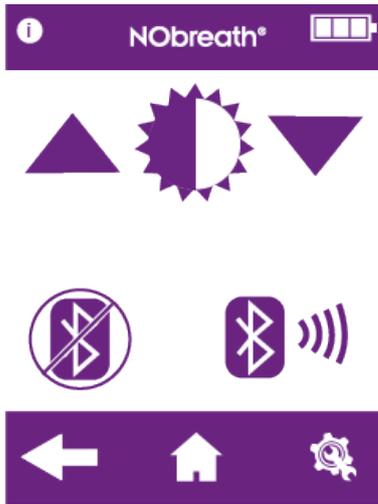


The NObreath® will begin sampling the atmosphere and an hourglass be shown onscreen.

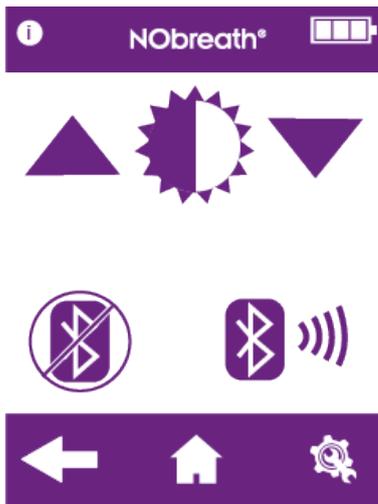


The result will be shown onscreen.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.

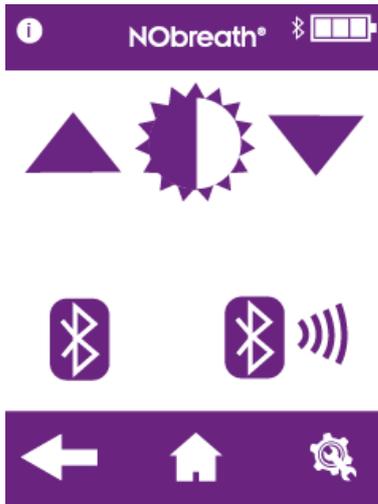


To adjust the brightness of the display, go to the 2nd page of the settings menu and use the arrows to increase/decrease the brightness of the screen.



Enable/disable Bluetooth

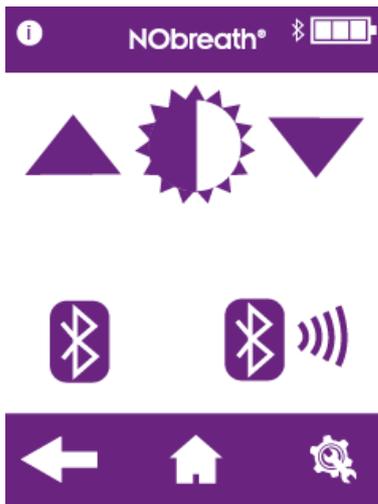
To enable Bluetooth, go to the 2nd page of the settings menu and press the enable/disable Bluetooth button.



Once Bluetooth is enabled, the Bluetooth symbol will no longer be crossed out on the 2nd page of the settings menu and a Bluetooth symbol will appear next to the battery status icon.

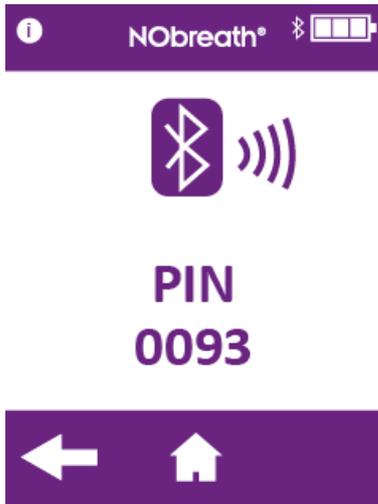
Press the icon again to switch Bluetooth off.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.



Bluetooth pairing

To pair a device with the NObreath®, go to the 2nd page of the settings menu and press the Bluetooth pairing icon.

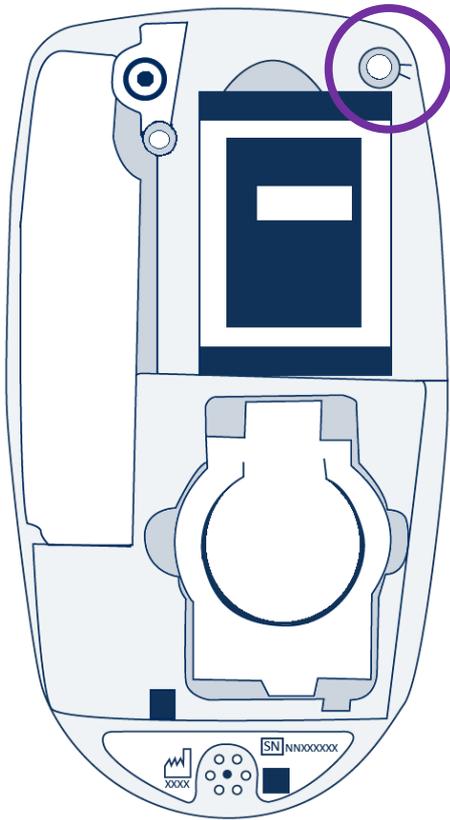


The screen will display the Bluetooth pairing PIN.

Please make sure the Bluetooth on the NObreath® and the other device is switched on in order to pair with the NObreath®.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.

Data Reset



To access the Data Reset button, first remove the back cover and the breath drying cartridge.

This will reveal the Data Reset button at the top right of the NObreath®.



Press and hold the Data Reset button for 5 seconds and the screen will reveal the reset icon.

NOTE: A data reset will erase all patient data from the device the PIN will be reset to the default, 0000.

Press the tick to confirm the data reset or cross to cancel.



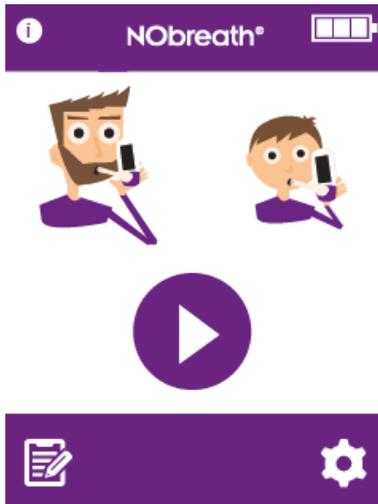
An egg timer will display onscreen as the NObreath® begins erasing all data.

NOTE: This can take up to 5 minutes to complete.



Once complete, the screen will prompt you to add the back cover again.

Ensure that you have re-inserted the breath drying cartridge and then reattach the back cover.



All data will be erased and the home screen will display once more.

Technical Specification

NObreath[®] monitor and dock

Concentration range		5-500ppb
Display		Full colour touchscreen
Detection principle		Electrochemical sensor
Repeatability		±5ppb of measured value ≤ 50ppb ±10% of measured value > 50ppb
Accuracy		±5ppb of measured value ≤ 50ppb ±10% of measured value > 50ppb
Power	NObreath[®] monitor	1 x main rechargeable Li-ion battery – Approx. 100 uses on fully charged battery 2 x Li-ion coin cell battery – Approx. 5 years Input: 5V, 0.5A
	NObreath[®] Dock	Mains powered Input: 5V, 0.5A Output: 5V, 0.5A
	Plug	Input: 100-240V ~ 50/60Hz., 0.2A Output: 5.0V, 1.0A
T₉₀ response time		≤10 seconds
Temperature	Operating	15-30°C
	Storage/transport	0-50°C
Humidity	Operating	20-80% RH (non-condensing)
	Storage/transport	5-95% RH (non-condensing)
Operating/transport/storage pressure		920-1080 mbar
Sensor operating life		5 years (subject to servicing)
Sensor sensitivity		1ppb
Sensor drift		<5% per annum
Dimensions		Approx. 90 x 159 x 59 mm
Weight		Approx. 400g
Materials	NObreath[®] monitor	Case: polycarbonate/ABS blend SteriTouch [®] anti-microbial additive
	NObreath[®] Dock	
Breath test time	Adult	12 seconds
	Child	10 seconds
	Ambient	30 seconds
Warm-up time		≤60 seconds
Maximum ambient operating level		350 ppb NO
CO cross interference		45 ppm ≤17.6 ppb

NOTE: Exhaled flow during FeNO measurement at 50ml/sec ±10% at 10cm H₂O

NObreath[®] mouthpiece

Infection control	An integrated infection control filter removes and traps >98% of airborne bacteria and >96% of viruses.
Dimensions	Approx. 180 x 28 x 22 mm
Weight	Approx. 14g
Materials	Polypropylene

Using the NObreath® with FeNOchart™

The NObreath® monitor is supplied with FeNOchart™ software, which allows patient data to be synchronised from the device to a computer, where results can be safely stored and analysed.

FeNOchart™ can be downloaded directly from www.nobreathfeno.com.

Insert the USB lead into the PC, and connect the other end to the rear of the docking station. Place the NObreath® into the docking station, connecting it to the micro USB in the base. Alternatively, the micro USB lead can be directly connected to the base of the NObreath® unit itself.

Before starting the software, ensure that the NObreath® is connected to the PC and switched on. Double click the FeNOchart™ icon on the PC to start the programme. Refer to the FeNOchart™ manual for how to operate the FeNOchart™ software.

Buttons Explained

Information		Retry		Change PIN	
Adult test		Save		Disable PIN	
Child test		Next screen		Enable PIN	
Demo mode		Previous screen		Change flow meter style	
Patient profiles		Settings		Ambient test	
Home button		Date & time		Disable Bluetooth	
Graph of results		Selected		Enable Bluetooth	
Delete patient		Increase		Service Area (See service manual)	
Confirm		Decrease			
Cancel		Test log			

Troubleshooting



The service date is due in ≤ 30 days.

This will be displayed every day until it has been reset by performing a calibration or sensor change.



365 days has elapsed since the last service.

This will be displayed every day until 395 days has surpassed or it has been reset by performing a calibration or sensor change.



395 days has elapsed since the last service.

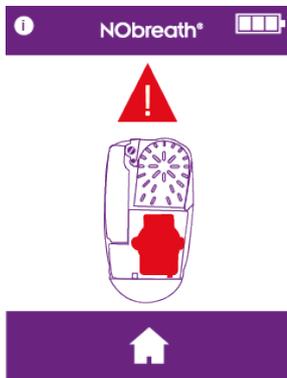
This will be displayed every day until it has been reset by performing a calibration or sensor change.

No tests can be performed until the monitor has been serviced.



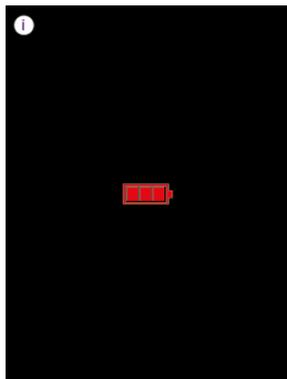
The back of the monitor is open.

Make sure the back of the unit is secure and the ¼ turn lock is closed to continue.



No sensor detected.

Verify the sensor is correctly inserted to continue.



The battery is flat.

Place the monitor in the charging dock or connect directly to the mains.

The NObreath® takes 8 hours to charge fully.

Safety Information

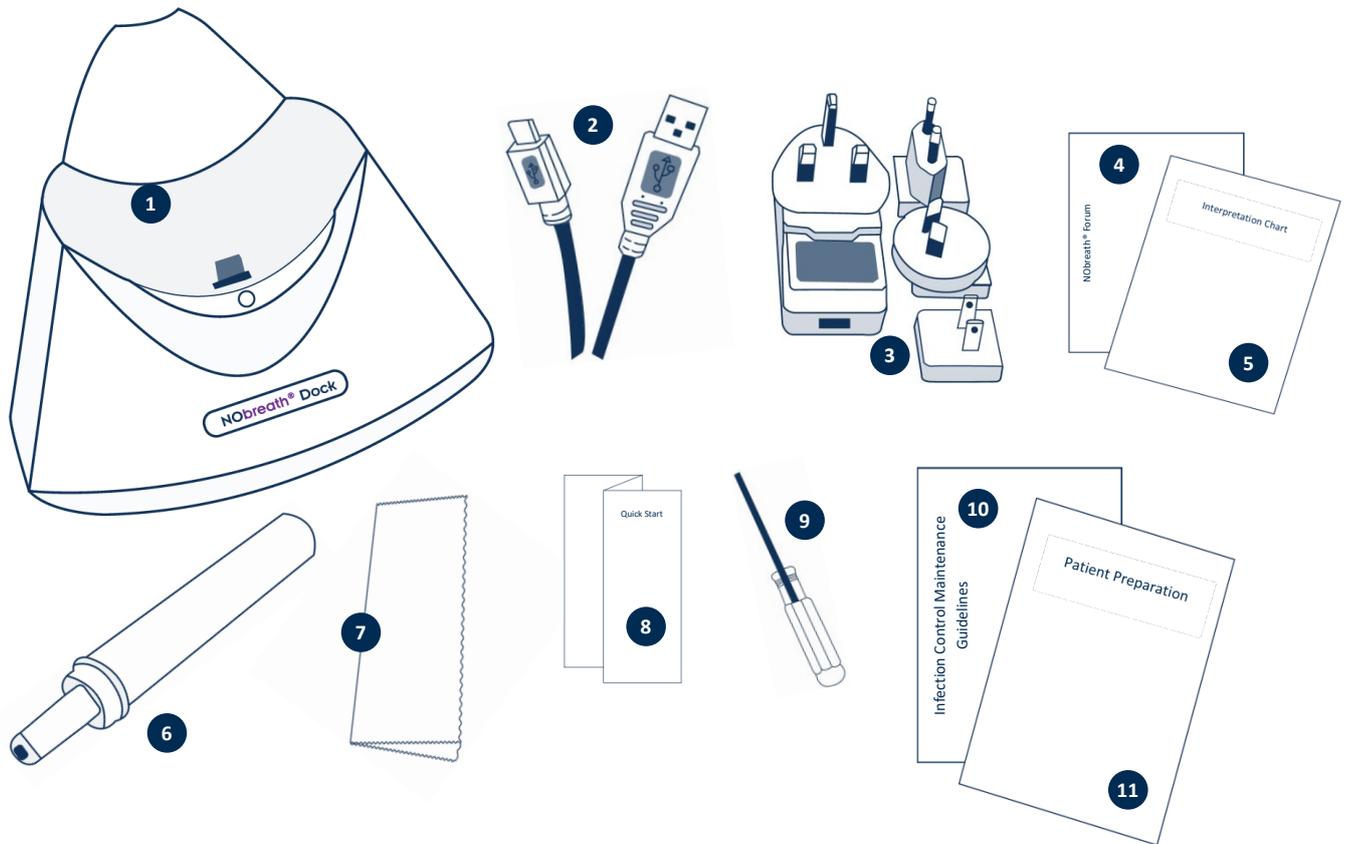
Degree of protection against electric shock	 Type BF applied part
Type of protection against electric shock	Internally powered equipment
Degree of protection against ingress of liquid	IPX0 – not protected against water ingress
Degree of safety application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable for use in the presence of flammable mixtures.
Refer to manual	
The device includes a Radio Frequency (RF) transmitter (Bluetooth)	
CE mark	
EC-REP	
Direct current	
Dispose of according to WEEE	
Serial number	
Manufactured by	
Manufacture date	
Bedfont® logo	

Electromagnetic Immunity

The NObreath® and NObreath® Dock comply with the directive EN60601-1-2:2015 4th edition electromagnetic compatibility.

Guidance and manufacturer's declaration: Electromagnetic immunity			
The NObreath® is intended for use in the electromagnetic environment specified below. The customer or the user of the NObreath® should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floor should be wood, concrete or ceramic floor tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-5	–	–	–
Surge IEC61000-4-5	–	–	–
Voltage dips, short interruptions and voltage variations on power supply. IEC 61000-4-11	–	–	–
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10V/m (1kHz 80%) 80MHz-2.7GHz 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	10V/m (1kHz 80%) 80MHz-2.7GHz 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	Portable and mobile RF communications equipment should be used no closer to the NObreath® than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol: 

Parts and accessories



1. NObreath® Dock
2. USB cable
3. Mains plug and universal adaptors
4. NObreath® Forum information
5. Interpretation chart
6. NObreath® mouthpiece

7. Microfiber cloth
8. Quick Start Guide
9. Screwdriver
10. Infection Control Maintenance Guidelines
11. Patient Preparation

Warranty

Bedfont® Scientific Limited warrants the NObreath® monitor, sensors and batteries excepted, to be free of defects in materials and workmanship for a period of 2 years from the date of shipment, subject to service and maintenance requirements.

The NO sensor is guaranteed for a period of 6 months only from the date of shipment from Bedfont®.

Bedfont's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned intact and prepaid, to Bedfont® or the local representative.

This warranty is automatically invalidated if the products are altered or tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident. At the end of the product's life, contact Bedfont® or its distributor for disposal instructions.

Single use consumables and accessories should be disposed of in line with local clinical waste guidelines.

Never dispose of any electronic instrument or batteries in domestic waste. At the end of the product's life, contact Bedfont® or its distributor for disposal instructions.

Returns

Please contact Bedfont® or its local distributor for instructions on returning goods.

Responsible Manufacturer and Contacts

Bedfont Scientific Ltd.
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Maidstone, Kent,
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United Kingdom

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